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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,282	04/14/2004	Donald Bellgrau	3921-1-1-1-1	7928

22442 7590 08/11/2009
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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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08/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,282	Applicant(s) BELLGRAU ET AL.	
	Examiner Sumesh Kaushal	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64,66, and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64,66, and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 03/26/09 has been acknowledged and fully considered.

Claims 64, 66, 68 and 69 are pending and are examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 64, 66 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Arai et al (PNAS 94(25):13862-13867, 1997), for the reason of record as set forth in the office action mailed on 09/26/08.

Response to Argument

The applicant argues that claim 64 has been amended to recite the induction of apoptosis in metastatic cancer cells. The applicant argues that Arai et al. does not contain any disclosure regarding metastatic cancer cells. The applicant argues that the cited art disclose that injection of FasL ligand-encoding DNA into a tumor results in regression of that local tumor but not in the metastatic cancer cells.

However the applicant's arguments are found not fully persuasive. The instant claims are drawn to a method of inducing apoptosis in metastatic cancer cells by administering a viral vector encoding Fas Ligand. Given the broadest reasonable interpretation the scope of invention as claimed encompasses direct injection of a viral vector encoding Fas Ligand into a metastatic cancer. Furthermore, the metastatic cancer is indistinguishable from any other cancer especially when the vector is directly injected.

The cited art clearly teaches that the gene transfer of Fas ligand induces tumor regression in-vivo. The cited art teaches that the Fas antigen is a cell surface receptor that transduces apoptotic signals into cells in response to the physiological ligand of Fas, Fas ligand (FasL), also known as CD95L or Apo-1L (page 13862, col.1). The cited

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art further teaches generation of recombinant ADV encoding FasL (ADV-FasL), see page 13863, col.1. The cited art further teaches regression of tumors after the ADV-FasL was injected into the tumors mediated (see page 13865, Fig 2 and 3). The cited art further teaches that human malignancies. HepG2 cells (HepG2), Hela cells (Hela), brain cancer (*three glioma cell lines G87, G138, and G373 and six melanoma cell lines M316, M342, M347, M444, M449, and M720*) express Fas and are susceptible to FasL mediated modulation (page 13866, fig-5). The cited art further teaches that FasL gene transfer can exert anti-tumor effects through two different mechanisms, either by induction of apoptosis through Fas-FasL engagement in Fas⁺ tumors or through its *ability to induce inflammation that is independent of Fas signaling to Fas⁻ tumor cells*. The cited art concluded that the ability to generate such potent inflammatory and apoptotic anti-tumor responses suggests that gene transfer of FasL may compensate for locally suppressive immune effects on tumor recognition and provide a useful molecular genetic intervention for malignancy (see Arai et al, discussion on pages 13865-67).

Prior art reference, in order to anticipate under 35 U.S.C. §102, must not only disclose all elements of claim within four corners of single document, but must also disclose those elements “arranged as in the claim”; this requirement, more accurately understood to mean “arranged or combined in the same way as in the claim,” applies to all types of claims and refers to need for anticipatory reference to show all limitations of claim arranged or combined in same manner recited in claim, not merely in particular order. *Net MoneyIN Inc. v. VeriSign Inc.*, 88 USPQ2d 1751 (Fed. Cir. 2008).

In the instant case the scope of invention as claimed encompasses direct injection of a viral vector encoding Fas-L into any metastatic cancer cell, which clearly anticipated by cited art of record, since a metastatic tumor is indistinguishable from a related cancer cells. In addition the cited art (Arai et al) clearly teaches that in the cells resistance to lysis by FasL, tumor regression was induced through and independent mechanism involving Fas-L inflammation and involved a potential ‘by standard effect’ in-vivo (see Arai et al, page 13865, col.1, Discussion, para.1). Furthermore, if the prior art structure is capable of performing the intended use, then it meets the claim. In a

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claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case the prior art clearly teaches the tumor regression via by standard effect" in-vivo. Therefore given the broadest reasonable interpretation the cited art clearly anticipate the invention as claimed.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sumesh Kaushal/
Primary Examiner, Art Unit 1633

Sumesh Kaushal
Primary Examiner
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